UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,543	02/12/2004	Harold M. Bates	C015043/0174944	9840

7590 11/15/2007

Stephen P. Gilbert, Esq.
BRYAN CAVE LLP
1290 Avenue of the Americas
New York, NY 10104

EXAMINER	
VENCI, DAVID J	
ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
11/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,543	BATES, HAROLD M.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 14, 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-13,15-30,32-34 and 36-88* is/are pending in the application.

4a) Of the above claim(s) *43-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-13,15-30,32-34 and 36-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-9,11-13,15-30,32-34 and 36-88* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges Applicants' reply, filed June 14, 2007, which amends claims 1 and 22.

Claims 1-9, 11-13,15-30, 32-34 and 36-88 are pending. Claims 43-88 are direct to a non-elected Invention and were withdrawn from consideration pursuant to 37 CFR 1.142(b) in the Office Action dated February 9, 2007.

Currently, claims 1-9,11-13,15-30,32-34 and 36-42 are under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 22-30,32-34 and 36-42 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

Insofar as claims 1 and 22 do not require "patients"[1], and therefore, patient "samples", Examiner interprets the verbiage in claims 1 and 22 as non-statutory "abstract ideas" in accordance with M.P.E.P. § 2106.

Claims 1-9,11-13,15-30,32-34 and 36-42 are rejected under 35 U.S.C. 101 because the claimed invention lacks credible utility.

Insofar as claims 1 and 22 do require "patients",[2] and therefore, patient "samples", claims 1 and 22 require, *inter alia*, patients having an "asymptomatic disease" (*i.e.*, asymptomatic coronary artery disease). Claims 1 and 22 create a semantic construct wherein a person simultaneously has a disease, yet is asymptomatic for that disease.

Applicant's specification asserts, *inter alia*, that methods incorporating "asymptomatic diseases" are useful for "discrimination between those who have coronary artery disease and those who do not" (see p. 15, lines 21-22).

According to M.P.E.P. 2107.02, Office determination of the credibility of Applicants' assertion of utility is based on whether the facts upon which Applicants' assertion is based are inconsistent with the logic underlying Applicants' assertion. In other words, credibility refers to the reliability of Applicants' assertion of utility in view of the logic and facts that Applicants offer to support Applicants' assertion of utility.

Here, Applicant's assertion of utility is premised on data obtained from a clinical study involving persons belonging to two semantic classes of individuals:

1. healthy (see *e.g.*, Table III, "Controls"; *see also*, p. 44, lines 3-4, "For purposes of evidencing the advantages of this invention, the assumption can be made that those in the control group are true negatives");
2. not healthy, *i.e.*, diseased (see *e.g.*, Table III, "Stable angina", "Unstable angina", "AMI")

[1] See Applicant's reply filed November 13, 2006, p. 6, first paragraph, "The methods of claims 1 and 22 comprise steps, *not patients*[...]"; second paragraph, "the methods of claims 43 and 66 comprise steps, *not patients*[...]" (emphasis in original) (paraphrasing mine).

Applicant's specification does not disclose any semantic class of individuals who are simultaneously healthy and not healthy (*i.e.*, individuals with asymptomatic diseases), much less any clinical data involving any asymptomatic disease, much less a useful method based on such (non-existent) clinical data.

---

[2] *Id.*

Claim Rejections - 35 USC § 112 – first paragraph

The following is a quotation of the first and second paragraphs of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9,11-13,15-30,32-34 and 36-42 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credibly asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112 – second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9,11-13,15-30,32-34 and 36-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claim 1 does not correspond to the method outcome. Specifically, the preamble intent of "analyzing a sample" for factors appears satisfied upon completion of step (a). Steps (b) and (c) appear to be extraneous, and their purposes in the overall method of "analyzing a sample" are not clear.

In claims 1 and 22, step (b), the phrase "based on" is indefinite. The identity of one or more standards for satisfaction of "based on" is not clear. The identity of one or more objects and/or steps required for "basing" or "relating" an abstract variable (*i.e.*, a "cut-point") using an inanimate noun (*e.g.*, an "acute phase reactant") is not clear.[3]

In claim 1(c)(i), the first instance of the phrase "based on" is indefinite. The identity of one or more objects referenced by "based on" is not clear. Whether "based on" references "comparison" OR/XOR "first value" is not clear. The identity of two or more parameters subject to "comparison" is not clear. Whether/how "the level of the atherogenic protein" obtained in step (a) provides basis for "first value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "first value") using a protein level (*i.e.*, the level of the atherogenic protein) is not clear.

---

[3] See *e.g.*, ***Discriminant Analysis, Linear***, in ENCYCLOPEDIA OF BIOSTATISTICS, Armitage & Colton eds., John Wiley & Sons (1998), (noting that abstract variables may be "based on" or "related to" an empirically-derived measurement (*e.g.*, activity of a protein, answers to a questionnaire, etc.)).

In claim 1(c)(i), the second instance of the phrase "based on" is indefinite. The identity of one or more objects referenced by "based on" is not clear. Whether "based on" references "comparison" OR/XOR "second value" is not clear. The identity of two or more parameters subject to "comparison" is not clear. Whether/how "the level of the acute phase reactant" obtained in step (a) provides basis for "second value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "second value") using a compound level (*i.e.*, the level of the acute phase reactant) is not clear.

In claim 1(c)(ii), the phrase "based on" is indefinite. The identity of one or more objects referenced by "based on" is not clear. Whether "based on" references "comparison" OR/XOR "third value" is not clear. The identity of two or more parameters subject to "comparison" is not clear. Whether/how "the levels of the atherogenic protein and acute phase reactant" obtained in step (a) provides basis for "third value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "third value") using two compound levels (*i.e.*, the levels of the atherogenic protein and acute phase reactant) is not clear.

In claim 1(c)(iii), the first instance of the phrase "based on" is indefinite. The identity of one or more objects referenced by "based on" is not clear. Whether "based on" references "comparison" OR/XOR "fourth value" is not clear. The identity of two or more parameters subject to "comparison" is not clear. Whether/how "the levels of the atherogenic protein and acute phase reactant" obtained in step (a) provides basis for "fourth value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "fourth value") using two compound levels (*i.e.*, the levels of the atherogenic protein and acute phase reactant) is not clear.

In claim 1(c)(iii), the second instance of the phrase "based on" is indefinite. The identity of one or more objects referenced by "based on" is not clear. Whether "based on" references "comparison" OR/XOR "fifth value" is not clear. The identity of two or more parameters subject to "comparison" is not clear.

Whether/how "the level of the anti-atherogenic protein" obtained in step (a) provides basis for "fifth value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "fifth value") using a protein level (*i.e.*, the level of the anti-atherogenic protein) is not clear.

In claim 1(c)(iv), the first instance of the phrase "based on" is indefinite. The identity of one or more objects referenced by "based on" is not clear. Whether "based on" references "comparison" OR/XOR "sixth value" is not clear. The identity of two or more parameters subject to "comparison" is not clear. Whether/how "the level of the atherogenic protein" obtained in step (a) provides basis for "sixth value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "sixth value") using a protein level (*i.e.*, the level of the atherogenic protein) is not clear.

In claim 1(c)(iv), the second instance of the phrase "based on" is indefinite. The identity of one or more objects referenced by "based on" is not clear. Whether "based on" references "comparison" OR/XOR "seventh value" is not clear. The identity of two or more parameters subject to "comparison" is not clear. Whether/how "the levels of the acute phase reactant and anti-atherogenic protein" obtained in step (a) provides basis for "seventh value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "seventh value") using two compound levels (*i.e.*, the levels of the acute phase reactant and anti-atherogenic protein) is not clear.

In claim 1(c)(v), the first instance of the phrase "based on" is indefinite. The identity of one or more objects referenced by "based on" is not clear. Whether "based on" references "comparison" OR/XOR "eighth value" is not clear. The identity of two or more parameters subject to "comparison" is not clear. Whether/how "the levels of the atherogenic protein and anti-atherogenic protein" obtained in step (a) provides basis for "eighth value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "eighth value") using two compound levels (*i.e.*, the levels of the acute phase reactant and anti-atherogenic protein) is not clear.

In claim 1(c)(v), the second instance of the phrase "based on" is indefinite. The identity of one or more objects referenced by "based on" is not clear. Whether "based on" references "comparison" OR/XOR "ninth value" is not clear. The identity of two or more parameters subject to "comparison" is not clear. Whether/how "the level of the acute phase reactant" obtained in step (a) provides basis for "ninth value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "ninth value") using a compound level (*i.e.*, the level of the acute phase reactant) is not clear.

In claim 1(c)(vi), the phrase "based on" is indefinite. The identity of one or more objects referenced by "based on" is not clear. Whether "based on" references "comparison" OR/XOR "tenth value" is not clear. The identity of two or more parameters subject to "comparison" is not clear. Whether/how "the levels of the atherogenic protein, acute phase reactant, and anti-atherogenic protein" obtained in step (a) provides basis for "tenth value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "tenth value") using three compound levels (*i.e.*, the levels of the atherogenic protein, acute phase reactant, and anti-atherogenic protein) is not clear.

In claim 1(c)(vii), the first instance of the phrase "based on" is indefinite. The identity of one or more objects referenced by "based on" is not clear. Whether "based on" references "comparison" OR/XOR "eleventh value" is not clear. The identity of two or more parameters subject to "comparison" is not clear. Whether/how "the level of the atherogenic protein" obtained in step (a) provides basis for "eleventh value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "eleventh value") using a protein level (*i.e.*, the level of the atherogenic protein) is not clear.

In claim 1(c)(vii), the second instance of the phrase "based on" is indefinite. The identity of one or more objects referenced by "based on" is not clear. Whether "based on" references "comparison" OR/XOR "twelfth value" is not clear. The identity of two or more parameters subject to "comparison" is not clear. Whether/how "the level of the acute phase reactant" obtained in step (a) provides basis for "twelfth value"

is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "twelfth value") using a compound level (*i.e.*, the level of the acute phase reactant) is not clear.

In claim 1(c)(vii), the third instance of the phrase "based on" is indefinite. The identity of one or more objects referenced by "based on" is not clear. Whether "based on" references "comparison" OR/XOR "thirteenth value" is not clear. The identity of two or more parameters subject to "comparison" is not clear. Whether/how "the level of the anti-atherogenic protein" obtained in step (a) provides basis for "thirteenth value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "thirteenth value") using a protein level (*i.e.*, the level of the anti-atherogenic protein) is not clear.

The preamble of claim 22 does not correspond to the method outcome. For example, the preamble of claim 22 recites a method for providing "a sample" information, while step (d) of claim 22 merely requires a step of providing "cut-point" information. Whether/how merely providing "cut-point" information amounts to a method of providing "a sample" information is not clear. One or more steps of providing "a sample" information appears omitted from claim 22.

In claim 22(c)(i), the first instance of the phrase "based on" is indefinite. Whether/how "the level of the atherogenic protein" obtained in step (a) provides basis for "first value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "first value") using a protein level (*i.e.*, the level of the atherogenic protein) is not clear.

In claim 22(c)(i), the second instance of the phrase "based on" is indefinite. Whether/how "the level of the acute phase reactant" obtained in step (a) provides basis for "second value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "second value") using a compound level (*i.e.*, the level of the acute phase reactant) is not clear.

In claim 22(c)(ii), the phrase "based on" is indefinite. Whether/how "the levels of the atherogenic protein and acute phase reactant" obtained in step (a) provides basis for "third value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "third value") using two compound levels (*i.e.*, the levels of the atherogenic protein and acute phase reactant) is not clear.

In claim 22(c)(iii), the first instance of the phrase "based on" is indefinite. Whether/how "the levels of the atherogenic protein and acute phase reactant" obtained in step (a) provides basis for "fourth value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "fourth value") using two compound levels (*i.e.*, the levels of the atherogenic protein and acute phase reactant) is not clear.

In claim 22(c)(iii), the second instance of the phrase "based on" is indefinite. Whether/how "the level of the anti-atherogenic protein" obtained in step (a) provides basis for "fifth value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "fifth value") using a protein level (*i.e.*, the level of the anti-atherogenic protein) is not clear.

In claim 22(c)(iv), the first instance of the phrase "based on" is indefinite. Whether/how "the level of the atherogenic protein" obtained in step (a) provides basis for "sixth value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "sixth value") using a protein level (*i.e.*, the level of the atherogenic protein) is not clear.

In claim 22(c)(iv), the second instance of the phrase "based on" is indefinite. Whether/how "the levels of the acute phase reactant and anti-atherogenic protein" obtained in step (a) provides basis for "seventh value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "seventh value") using two compound levels (*i.e.*, the levels of the acute phase reactant and anti-atherogenic protein) is not clear.

In claim 22(c)(v), the first instance of the phrase "based on" is indefinite. Whether/how "the levels of the atherogenic protein and anti-atherogenic protein" obtained in step (a) provides basis for "eighth value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "eighth value") using two compound levels (*i.e.*, the levels of the acute phase reactant and anti-atherogenic protein) is not clear.

In claim 22(c)(v), the second instance of the phrase "based on" is indefinite. Whether/how "the level of the acute phase reactant" obtained in step (a) provides basis for "ninth value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "ninth value") using a compound level (*i.e.*, the level of the acute phase reactant) is not clear.

In claim 22(c)(vi), the phrase "based on" is indefinite. Whether/how "the levels of the atherogenic protein, acute phase reactant, and anti-atherogenic protein" obtained in step (a) provides basis for "tenth value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "tenth value") using three compound levels (*i.e.*, the levels of the atherogenic protein, acute phase reactant, and anti-atherogenic protein) is not clear.

In claim 22(c)(vii), the first instance of the phrase "based on" is indefinite. Whether/how "the level of the atherogenic protein" obtained in step (a) provides basis for "eleventh value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "eleventh value") using a protein level (*i.e.*, the level of the atherogenic protein) is not clear.

In claim 22(c)(vii), the second instance of the phrase "based on" is indefinite. Whether/how "the level of the acute phase reactant" obtained in step (a) provides basis for "twelfth value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "twelfth value") using a compound level (*i.e.*, the level of the acute phase reactant) is not clear.

In claim 22(c)(vii), the third instance of the phrase "based on" is indefinite. Whether/how "the level of the anti-atherogenic protein" obtained in step (a) provides basis for "thirteenth value" is not clear. The identity of one or more objects and/or steps required for "basing" an abstract variable (*i.e.*, "thirteenth value") using a protein level (*i.e.*, the level of the anti-atherogenic protein) is not clear.

In claim 22, step (d), the infinitives "to permit" and "to assess" are indefinite. Whether the act or process of "permitting" or "assessing" are completed or performed, or merely intended, is not clear. The identity of object(s) and/or step(s), if any, required for performing "permitting" or "assessing" is/are not clear.

Response to Arguments

Claim Rejections - 35 USC § 101 – subject matter

In prior Office Action, claims 1-9,11-13,15-30,32-34 and 36-42 were rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

In response, Applicant provides substantial amendment to the preambles of independent claims 1 and 22. In addition, Applicant provides argumentation premised on the assertion that Applicant's invention definitively requires a "sample" obtained from a "human patient".

With respect to independent claim 1 and depending claims thereof, and notwithstanding outstanding issues of claim indefiniteness[4], Applicant's amendment to the preamble of claim 1 is sufficient to overcome this rejection.

With respect to independent claim 22 and depending claims thereof, Applicant's amendment and argumentation have been carefully considered but are not persuasive for the following reasons:

1. Independent claim 22 does not definitively require "a sample" obtained from a "human patient". Rather, claim 22 requires a step of obtaining a "level".

2. Consistent with claim 22, Applicant's specification provides support for obtaining a "level" by "consulting[...] a database or library of substances to extract previously obtained level of substance information", which Examiner posits, does not appear to require any step that Examiner could possibly construe as ostensibly manipulating a physical "sample" obtained from a "human patient" (see specification, sentence bridging pp. 25-26) (paraphrasing mine).

[4] See *Claim Rejections - 35 USC § 112 – second paragraph.* Claim 1 is rejected because the preamble of claim 1 does not correspond to the method outcome. Specifically, the preamble intent of "analyzing a sample" for factors appears satisfied upon

3. Consistent with both claim 22 and Applicant's specification, Applicant said claim 22 does not require a "patient".[5] Thus, the claims, specification and Applicant's own argumentation appear to disclaim "patients" from Applicant's invention.

Claim Rejections - 35 USC § 101 – utility

In prior Office Action, claims 1-9,11-13,15-30,32-34 and 36-42 were rejected under 35 U.S.C. 101 because the claimed invention lacks credible utility.

In response, Applicant transfers a misunderstanding of "asymptomatic disease" to Examiner, while looking to Thilly (US 6,994,962), Braun *et al.* (US 6,821,739) and Moreno *et al.* (US 6,816,743) to impute some utility into the instant claims.

Applicant's response is not persuasive.

The art is replete with cases having asymptomatic diseases, and the clarity of it's definition has not been raised in any Office Action. Unfortunately, Applicant's specification does not disclose such a case of an individual or group of individuals who are simultaneously healthy and not healthy (*i.e.*, individuals with asymptomatic diseases), much less any clinical data involving any asymptomatic disease, much less a useful method based on such (non-existent) clinical data. Rather, Applicant's specification discloses data obtained from cases belonging to two semantic classes: healthy XOR not healthy.

In other words, Applicant's assertion of utility is premised on (*i.e.*, substantiated with) bad data obtained from a bad clinical study involving the wrong persons.[6] See Kaplan & Sadock.

---

completion of step (a). Steps (b) and (c) appear to be extraneous, and their purposes in the overall method of "analyzing a sample" are not clear.

[5] See *supra*, note 1.

[6] According to M.P.E.P. 2107.02, Office determination of the credibility of Applicants' assertion of utility is based on whether the facts upon which Applicants' assertion is based are inconsistent with the logic underlying Applicants' assertion. In other words,

Conclusion

No claims are allowable at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Assistant Examiner
Art Unit 1641

djv

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

credibility refers to the reliability of Applicants' assertion of utility in view of the logic and facts that Applicants offer to support Applicants' assertion of utility.